UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/645,822 | 08/22/2003 | Nickolai Alexandrov | 2750-1571P | 7309 |

2292 7590 07/21/2011

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

| EXAMINER | |
|---|---|
| BUI, PHUONG T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 07/21/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/645,822 | ALEXANDROV ET AL. |
| | Examiner | Art Unit |
| | PHUONG BUI | 1638 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 6-20* is/are pending in the application.

4a) Of the above claim(s) *11,12,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-10,13,14 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

| Attachment(s) | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ . |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 6) ☐ Other: _____. |

## DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment filed May 12, 2011. Claims 1, 2 and 6-20 are pending. Claims 11, 12, 15 and 16 are withdrawn from examination as being drawn to nonelected inventions. Claims 1, 2, 6-10, 13, 14 and 17-20 are examined in the instant application.

SEQ ID NO:16117 encoding SEQ ID NO:16118 was first disclosed in Application No. 10/621442 filed July 18, 2003. It is unclear whether the recitation of "Note: the GI number noted in the above table was annotated in NCBI as a 'putative cyclin' as of January 2, 1998" for Application No. 09/513966 is part of the original disclosure for said application or a later-added statement. Until the date of said recitation is established, the priority benefit of Application No. 09/513966 filed February 25, 2000 cannot be granted.

All previous rejections not set forth below have been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL.

### *Claim Rejections - 35 USC § 112, second paragraph*

2. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, it is unclear how "functions as a cyclin" is defined. The specification does not define a function for cyclin; and it is unclear how "functions as a

cyclin" can be determined for sequences which hybridize to a sequence having 95% sequence identity to a sequence encoding SEQ ID NO:16118, fragments of complements of SEQ ID NO:16117 and fragments of SEQ ID NO:16117.

In claim 1(c), if SEQ ID NO:16118 functions as a cyclin, it does not appear Applicant intends for the non-coding sequence (a sequence which hybridizes to a sequence encoding SEQ ID NO:16118) to also function as a cyclin. Moreover, a sequence which hybridizes to degenerant DNA sequences encoding SEQ ID NO:16118 would not hybridize to genomic sequences including SEQ ID NO:16117. There appears to be a typographical error in claim 1(c): "(a) – (c)" should be "(a) – (b)".

In claim 2(a), it is unclear whether the recitation of "functions as a cyclin" applies to a sequence having 95% sequence identity to SEQ ID NO:16117, or only to the fragment.

In claim 2(b), it is suggested "a full-length complement" be amended to "the full-length complement" because there is only one full-length complement of SEQ ID NO:16117.

In claim 2(b), it does not appear Applicant intends for the non-coding sequence (a fragment of the full-length complement) to also function as a cyclin.

In claim 13, it is suggested "an" be amended to "the" for proper antecedence. This rejection was previously made and has not been addressed.

In the previous action, in claim 20, it was suggested "a plant" be amended to "the plant" for proper antecedence. However, this is incomplete because claim 20 should be

amended to "the plant cell according to claim 18". The Office regrets any inconvenience to Applicant.

Clarification and/correction is required.

***Claim Rejections - 35 USC § 101***

3. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The specification discloses SEQ ID NO:16117 was isolated from *Arabidopsis thaliana* but does provide a function or utility for SEQ ID NO:16117. The protein expressed by SEQ ID NO:16117 may have some function in *Arabidopsis*. However, that function is not known or disclosed. It is also not known how SEQ ID NO:16117 can be used to achieve a useful outcome. It is apparent that further research is required before the claimed polypeptide would be of benefit to the public. However, the courts have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, the claimed invention is not refined and developed to the point where substantial benefit exists, as no guidance is provided as to how SEQ ID NO:16117 should be used to achieve a useful outcome. The assignment of “cyclin” to SEQ ID NO:16118 based upon sequence alignment does not provide utility for the claimed invention because

Applicant does not disclose how a cyclin of SEQ ID NO:16118 can be used to achieve a useful outcome. There is no well-established utility for a cyclin or a cyclin of SEQ ID NO:16118. Accordingly, the claimed invention lacks substantial utility. Since SEQ ID NO:16117 lacks utility, its complementary sequence, sequences which hybridize at 5-10C below the melting temperature, a sequence having 95% sequence identity and fragments thereof also lack utility.

Additionally, there also is no well-established utility for SEQ ID NO:16117. SEQ ID NO:16117 does not have a well-established utility such as antisense, protein expression, antibody production or diagnostic purposes because the sequence does not have utility for the reasons indicated above. Thus, the claimed invention lacks utility under current utility guidelines. (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Claims 1, 2, 6-10, 13, 14 and 17-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant traverses, stating that the claimed sequence was identified as having similarity to a cyclin; and residues 5-124 of SEQ ID NO:16118 are a cyclin_N domain.

Applicant's traversal is unpersuasive because it is unclear whether one skilled in the art can used a cyclin of SEQ ID NO:16118 to achieve a useful outcome. First of all, residues 5-124 of SEQ ID NO:16118 is not identified as a cyclin_N domain in the instant application. Secondly, while cyclins are known in the art as a protein whereby its

expression level fluctuates in the cell cycle, and cyclins are associated with cyclin-dependent kinases (CDK), it is unclear whether the cyclin of SEQ ID NO:16118 is associated with a CDK, and what substrate the cyclin-CDK complex would phosphorylate to result in a plant having a characteristic or phenotype which would be of benefit to the public. Different cyclin-CDK complexes phosphorylate different substrates (see Applicant's Pfam attachment filed May 12, 2011). Placing a protein in a particular group such as cyclin, does not immediately impart utility to said protein if the utility for the members of said group cannot be reasonably ascertained by one skilled in the art at the time the invention was made. Because the utility of a cyclin of SEQ ID NO:16118 is not disclosed in the specification, Applicant is relying on well-established utilities for cyclins. There is no evidence that cyclins have a well-established utility at the time the invention was made; it is unclear whether all cyclins have the same function; and it is not known whether a cyclin of SEQ ID NO:16118 would have the same utility as those known in the art. Accordingly, this rejection is maintained.

***Claim Rejections - 35 USC § 112, first paragraph***

4. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In addition to lacking enablement because the claimed invention lacks utility, the recitations of 95% sequence identity, complementary sequences, sequences which

hybridize at 5-10C below the melting temperature and a fragment thereof are also not enabled for the following reasons. With regard to 95% identity and hybridization at 5-10C below the melting temperature, these recitations encompass unspecified base substitutions, deletions, additions, and/or combinations thereof without any guidance as to what functional activity should be retained. Applicant provides no working example of sequences having 95% sequence identity or sequences which hybridizes to SEQ ID NO:16117 at 5-10C below the melting temperature. A sequence which hybridizes to degenerant DNA encoding SEQ ID NO:16118 is the noncoding sequence and also would not hybridize to genomic DNA. Applicant does not teach which region(s) of SEQ ID NO:16117 must be conserved or can tolerate mutations to retain the undisclosed functional activity. The claims encompass inoperable embodiments but the specification provided no guidance or working example as to how such inoperable embodiments can be readily eliminated without undue experimentation. While one skilled in the art can readily make mutations to SEQ ID NO:16117, further guidance is needed as to what mutations would not abrogate its activity, however such activity is defined. Fragments of sequences having 95% sequence identity to SEQ ID NO:16117 and functioning as a cyclin are not enabled because Applicant does not define cyclin function; Applicant does not provide working examples of fragments having cyclin function; and while SEQ ID NO:16118 has been identified as a cyclin because of a particular domain, a cyclin domain has not been shown to be sufficient to function alone as a cyclin. It should be noted no function is recited for sequences having 95% sequence identity to SEQ ID NOs. 16117 and 16118. One skilled in the art cannot

make and use a sequence having no recited function; one skilled in the art cannot make and use sequences having 95% sequence identity to SEQ ID NOs. 16117 and 16118 which does not have the functional activity of SEQ ID NOs. 16117 and 16118; and one skilled in the art would not be able to eliminate inoperable embodiments within said 95% sequence identity genus which does not have the desired activity without undue experimentation since no activity is recited. Accordingly, Applicant has not enabled the claimed invention without excessive burden and undue experimentation.

Applicant traverses primarily that degeneracy in the gene code encoding SEQ ID NO:16118 provides for nucleic acid sequences having 95% sequence identity to SEQ ID NO:16117; the attached Pfam statement (Wikipedia) indicates cyclins generally contain at least one cyclin domain, an N-terminus cyclin domain and/or a C-terminus cyclin domain; the cyclin_N domain is at residues 5-124; and a skilled artisan would understand that amino acid substitutions would not be made in these conserved regions or in any other known domains that were identified in the sequences.

Applicant's traversals have been considered but are not deemed persuasive because Applicant is arguing limitations not present in the claims. The sequences having 95% sequence identity to SEQ ID NOs. 16117 and 16118 are not required to retain any functional activity. The claims are not limited to degenerant DNA sequences encoding SEQ ID NO:16118. The attached Pfam statement was not available at the time the invention was made and thus cannot be considered. The claims do not require that residues 5-124 of SEQ ID NO:5-124 of SEQ ID NO:16118 be retained. Moreover, residues 5-124 of SEQ ID NO:16118 has not been identified as the cyclin_D domain in

the instant application. It is not known in the art at the time the invention was made what other conserved domains must be retained for "cyclin function". Accordingly, this rejection is maintained.

5. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by amendment.

Applicant does not disclose a representative number of species which hybridizes to sequences within the 95% sequence identity to a sequence encoding SEQ ID NO:16118 and their complements which function as a cyclin. The sequence encoding SEQ ID NO:16117 was obtained from *Arabidopsis thaliana*. While one skilled in the art can generate a population of sequences within the 95% genus, their complements and sequences which hybridize to them, one cannot reliably predict which sequence(s) within the genus will function as a cyclin when expressed. Applicant does not disclose a single mutated sequence which has the cyclin function. Applicant provides no guidance as to the structure of other sequences within the claimed genus which will function as a cyclin. The genus of 95% sequence identity and sequences which hybridize to them encompass sequences from other undisclosed species, and mutants and allelic variants. The implication is that structural variants exist in nature, yet no structural variant has been disclosed. There is also the implication there is a gene and a protein

other than that disclosed which exists in nature, but the structure thereof is not known. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and sequences within the 95% genus from other plants and organisms having the cyclin function, absent further guidance. One skilled in the art cannot reliably determine the structures of other cyclins based upon the disclosure of SEQ ID NOs:16117 and 16118. Because sequences having 95% sequence identity and function as a cyclin lack adequate written description, their fragments and complements also lack adequate written description. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

***Claim Rejections - 35 USC § 102***

6. Claims 1, 2, 6, 8-10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (Nature, Vol. 402, pp. 761-768, 16 Dec 1999 (previously cited)); sequence alignment Lin et al, UniProt_201006 Database, Accession Nos. Q8RWV3, O48710, Q94L33, Nature, Vol. 402, pp. 761-768, 16 Dec 1999, see Result 1 (previously cited)). Lin teaches a nucleic acid sequence encoding an amino acid sequence which has 100% sequence identity to Applicant's SEQ ID NO:16118. Lin also teaches a vector, heterologous promoter, host cell, a method of introducing a nucleic acid into a host cell and a method of transforming a transgenic plant cell, plant, progeny, seed and vegetative tissue. Accordingly, Lin anticipates the claimed invention.

Applicant traverses that Applicant claims priority to Application No. 60/128234, which was filed on April 6, 1999 and because Lin was published December 16, 1999, the priority claim of the instant application pre-dates Lin.

Applicant's traversal has been considered but is deemed unpersuasive because Application No. 60/128234 does not disclose SEQ ID NO:16118 is a cyclin. Accordingly, this rejection is maintained.

7. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP1033405, published 06 September 2000, SEQ ID NO:16179 (N)). Alexandrov teaches SEQ ID NO. 16179 which has 100% sequence identity to SEQ ID NO:16117. Alexandrov further teaches a vector, host cell, method of introducing a nucleic acid molecule, method of transforming and plant. Accordingly, Alexandrov anticipates the claimed invention.

Applicant traverses that Applicant claims priority to Application No. 09/513996, which is the US equivalent of EP1033405, and since Alexandrov was published September 6, 2000, the priority claim of the instant application pre-dates Alexandrov.

Applicant's traversal has been considered but is deemed unpersuasive because the priority benefit of Application No. 09/513996 has not been established as indicated above. Accordingly, this rejection is maintained.

***Remarks***

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHUONG BUI whose telephone number is (571)272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/
Primary Examiner, Art Unit 1638